UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

In re: PHARMACEUTICAL INDUSTRY AVERAGE WHOLESALE PRICE LITIGATION	**MDL No. 1456** **Master File No. 01-CV-12257-PBS** **Subcategory Case No. 06-11337** **Hon. Patti B. Saris**
THIS DOCUMENT RELATES TO: *United States of America ex rel. Ven-A-Care of the Florida Keys, Inc., et al. v. Dey, Inc., et al.*, Civil Action No. 05-11084-PBS	**Magistrate Judge Marianne B. Bowler**

AFFIDAVIT OF PAMELA R. MARRS IN SUPPORT OF DEY, INC., DEY, L.P., AND DEY L.P., INC.'S MOTION FOR PARTIAL SUMMARY JUDGMENT

STATE OF CALIFORNIA)
) ss.:
COUNTY OF NAPA)

Pamela R. Marrs, being duly sworn, deposes and says:

1. I am the Senior Vice-President and Chief Financial Officer of Defendant Dey, Inc ("Dey").

2. Except where otherwise indicated, I make this Affidavit from my personal knowledge. The source of my knowledge is my employment experience with Dey and my review of Dey's files.

3. I submit this Affidavit on behalf of Dey, Inc., Dey, L.P., and Dey L.P., Inc. (collectively, "Dey"), in support of Dey's Motion for Partial Summary Judgment.

Dey's History

4. Dey, Inc. is a Delaware corporation with its principal place of business at 2751 Napa Valley Corporate Drive in Napa, California. Dey, Inc. is the general partner of Dey, L.P. which is engaged in the "development, manufacturing and marketing of prescription drugs used to treat selected respiratory diseases and allergies."

5. Dey was founded in 1978 by four entrepreneurs as a small, start-up company selling generic respiratory medications.

6. Dey's first products were unit-dose sodium chloride solution inhalation solutions ("saline solutions") which the company began to sell in 1978. Dey continues to sell all of these products presently.

7. From 1978 until the late 1980s, Dey's sales, marketing, and distribution facilities were in Texas and its manufacturing plant was in Concord, California.

8. During this time period, Dey principally sold saline solutions and other generic respiratory medications in unit dose vials, including acetylcysteine, introduced in 1986, and metaproterenol, introduced in 1987.

9. In its first decade, Dey's principal customers were hospitals.

10. In the late 1980s, Dey relocated to a site in Napa, California.

11. In 1989, Dey moved its manufacturing, sales, and marketing functions to the Napa site, but kept its distribution operations in Texas.

Dey's Albuterol

12. Once Dey moved its manufacturing facilities to Napa and received FDA approval, it then had the capacity to manufacture albuterol sulfate in unit dose vials.

13. Albuterol sulfate ("albuterol") is a respiratory inhalation drug that is used for the relief of bronchospasm in patients with reversible obstructive airway disease and acute attacks of bronchospasm.

14. Dey's principal generic albuterol product is a liquid unit dose solution that is administered via a nebulizer, which is a piece of durable medical equipment.

15. Dey submitted an abbreviated new drug application ("ANDA") for albuterol unit dose in the later 1980s.

16. Dey's application was approved in 1992 and in March 1992, Dey became the first pharmaceutical manufacturer to launch a generic albuterol unit dose solution and was the only generic manufacturer in the market for over one year after launch.

17. Not only was Dey's albuterol product the first generic unit dose albuterol to market, it was the first BAC-preservative-free albuterol unit dose solution on the market.

18. Dey became known and respected for the following breakthrough features of its products:

- The replacement of screwtop bottles with the first plastic unit-dose vials;
- Patient-friendly TwistFlex™ vials to reduce cross-contamination;
- BAC-preservative-free.

19. With the launch of albuterol, Dey began breaking into other markets, including homecare and to a lesser extent, retail.

20. Dey did not have a large retail presence, in part, because it did not have a full line of albuterol products available for sale as other larger manufacturers did.

21. Accordingly, Dey's retail sales for albuterol accounted for a small percentage of sales in the first few years after albuterol launched.

22. Dey still manufactures and sells unit dose albuterol although it is not profitable. Currently, there are six other companies that market generic versions of albuterol.

23. In the mid-1990s, Dey tried to expand its albuterol line of products so that it could compete better with the larger manufacturers.

24. Dey therefore launched its multi dose albuterol product in March 1996 and its metered dose inhaler albuterol product in November 1996.

25. Dey did not manufacture either of these products, but purchased them from other manufacturers.

26. When Dey entered the multi dose albuterol market, there were already a number of competitors selling the same product.

27. Dey stopped selling multi dose albuterol in mid-2003.

28. When Dey entered the metered dose inhaler market, there were already a number of competitors selling the same product.

29. Dey stopped selling metered dose inhaler in early 2003.

Dey's Cromolyn

30. In addition to albuterol, Dey was also pursuing opportunities to launch other generic respiratory inhalation solutions in the late 1980s and early 1990s.

31. Dey thus submitted an ANDA for cromolyn sodium, which was the next respiratory inhalation solution coming off patent.

32. Cromolyn sodium ("cromolyn") is a prophylactic respiratory inhalation drug used to treat patients with bronchial asthma. Dey's generic cromolyn product is a liquid unit dose solution that is administered via a nebulizer, which is a piece of durable medical equipment.

33. Dey launched its cromolyn product in May 1994. As with unit dose albuterol, Dey was the first generic cromolyn on the market.

34. Currently, there are at least seven companies that sell generic versions of cromolyn.

35. Dey stopped manufacturing cromolyn in February 2008 as it was unable to sustain a profit on sales.

Dey's Ipratropium

36. In January 1997, Dey launched a generic unit dose ipratropium bromide solution.

37. Ipratropium bromide ("ipratropium") is a respiratory inhalation drug used for the maintenance treatment of bronchospasms associated with Chronic Obstructive Pulmonary Disease ("COPD"), which is a term used to describe a number of airway diseases, including both chronic bronchitis and emphysema. Ipratropium is classified as an anticholinergic bronchodilator because it works by preventing the bronchial smooth muscle from constricting.

38. Dey's generic ipratropium product is a unit dose liquid solution that is administered via a nebulizer, which is a piece of durable medial equipment.

39. Dey continues to sell ipratropium at a close to break even profit level. Currently, there are at least seven other companies that sell generic versions of ipratropium.

Further Evolution of Dey's Business

40. By the late 1990s, with increased competition in the generic markets for albuterol, cromolyn, and ipratropium and the quickly eroding profit margins on those drugs, as well as the limited number of respiratory drugs delivered via nebulization coming off patent in

future years, Dey decided to switch its business model to focusing on developing, manufacturing and selling branded inhalation solutions.

41. Dey launched two branded inhalation solutions, AccuNeb and DuoNeb, in 2001.

42. With the launch of these branded products, Dey's marketing and sales efforts were almost entirely focused on promoting Dey's brands instead of its generics.

43. Dey has complied with its obligations and provided its AMP to CMS each quarter for each of the Subject Drugs.

44. Beginning in the first quarter of 2004, Dey reported its ASPs to CMS.

45. Throughout the relevant time period, Dey reported WACs for the Subject Drugs to pricing compendia such as First DataBank, RedBook, and Medispan.

Dey's Subject Drugs

46. All of the Subject Drugs are generic drugs.

47. The Subject Drugs are sold under a number of National Drug Codes (NDCs).

48. NDCs are 11-digit codes that uniquely identify the drug by manufacturer, active ingredient, and package size. If the packaging of a drug is changed, new NDCs must be assigned; these are often referred to as successor NDCs.

Information Provided by Dey in Response to Subpoenas

49. The HHS-OIG issued a first subpoena to Dey on or about October 31, 1997 and a second subpoena on or about July 27, 2000.

50. Over an eight year period from October 1997 to September 2005, Dey produced or made available for inspection approximately 2.3 million pages of documents on at

least eight separate occasions to the HHS-OIG (most of which were also produced to Ven-A-Care in connection with the Texas and/or Florida pricing litigations).

51. As of December, 1997, Dey had produced 2697 pages of documents, which included various contract awards listing contract prices and other pricing information for many of the Subject Drugs.

This the 25 day of June, 2009.

Pamela R. Marrs

CALIFORNIA JURAT WITH AFFIANT STATEMENT

☑ See Attached Document (Notary to cross out lines 1–6 below)
☐ See Statement Below (Lines 1–5 to be completed only by document signer[s], *not* Notary)

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Signature of Document Signer No. 1 | Signature of Document Signer No. 2 (if any)

State of California

County of NAPA

Subscribed and sworn to (or affirmed) before me on this

25th (Date) day of June (Month), 2009 (Year), by

(1) Pamela R. Marrs (Name of Signer),

proved to me on the basis of satisfactory evidence to be the person who appeared before me (.) (;)

(and

(2) none (Name of Signer),

proved to me on the basis of satisfactory evidence to be the person who appeared before me.)

Signature Nancy Kendall (Signature of Notary Public)

NANCY KENDALL
COMM. #1721827
Notary Public-California
NAPA COUNTY
My Comm. Exp. Feb 26, 2011

Place Notary Seal Above

OPTIONAL

Though the information below is not required by law, it may prove valuable to persons relying on the document and could prevent fraudulent removal and reattachment of this form to another document.

Further Description of Any Attached Document

Title or Type of Document: Affidavit

Document Date: — Number of Pages: 7

Signer(s) Other Than Named Above: none

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RIGHT THUMBPRINT OF SIGNER #2
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